Remarks

Claim 12 has been canceled without prejudice or disclaimer. No new matter has been entered.

Claims 25-36 are pending.

I. Claims

The Examiner has advised Applicant that if claim 25 should be found allowable, that claims 26 and 27 will subsequently be objected to under 37 C.F.R. § 1.75 as being alleged substantial duplicates of the allowed claim. Applicant will address this issue once the Examiner has made a formal objection or rejection of these claims.

II. Utility/Enablement Rejections Under 35 U.S.C. §§ 101/112, First Paragraph

a. The Examiner has rejected claims 25-36 under 35 U.S.C. § 101, for alleged lack of a specific and substantial and credible asserted utility or well-established utility. In particular, the Examiner alleges that additional research is necessary to "identify the relevant disorders in addition to the relevant tissues, cells, and body fluids" in order to use the instatne invention. *See*, paragraph spanning pages 4-5.

Applicant respectfully disagrees and traverses this rejection.

In order to find that an asserted utility is not specific or substantial or well-established, the burden is on the Examiner to make a *prima facie* showing that it more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the Applicant to be specific or substantial or well-established. *See*, M.P.E.P. § 2107.02(IV); Utility Examination Guidelines at 1098, col. 3. Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established; (2) support for the factual findings relied upon in reaching this conclusion; and (3) and evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See id.*

Applicant contends that the Examiner has provided no evidence or support that (1) the logic underlying Applicant's assertions of utility is seriously flawed, (2) the facts upon which Applicant bases the assertions of utility are inconsistent with the logic underlying

the assertions, or that (3) the statements of asserted utility in the present application would be considered "false" by a person of ordinary skill in the art. The Examiner has simply provided generalized statements that the instant specification does not provide any evidence that the claimed polypeptide is indeed involved in any of utilities disclosed in the specification and that "basic research" is required to prove the assertions made in the specification. *See*, pages 4-6.

Regarding substantial utility, the M.P.E.P. § 2107.01 on page 2100-32 states that,

> Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful.

Moreover, the M.P.E.P. states that if a utility has a "real-world" use that it should be considered to be substantial. In particular, M.P.E.P. § 2107.01 at page 2100-32 states "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, as least with regard to defining a 'substantial' utility."

Contrary to the Examiner's arguments, Applicant contends that the specification does set forth a specific, substantial, and credible utility. As a preliminary matter, Applicant disagrees that the specification indicates "that the gene expression product occurs in tissues, cell types and body fluids besides breast tissue." *See*, Office Action at paragraph spanning pages 4-5. In fact, Applicant notes that the specification describes how the polypeptides of the invention are primarily expressed in one specific tissue type, breast tissue. *See*, specification, e.g., at page 49, line 9. Thus, no further experimentation is required "before polynucleotides and polypeptides of the invention could be used as reagents for identification of biological samples and for diagnosis of diseases and conditions," including breast cancer *See*, paragraph spanning pages 4-5. Thus, the specification sets forth that the polypeptides of the invention may be useful, for example, in the diagnosis and/or treatment of those specific cancers.

In addition, based on the expression of the polypeptides of the instant invention in breast tissue, the specification discloses that these polypeptides are useful for the diagnosis and/or treatment of breast cancer. Thus, Applicant asserts that the one of skill in the art would clearly find this asserted utility to be specific and require no further "basic

research". In addition, since the diagnosis and/or treatment of a specific cancer, such as breast cancer, is a certainly a "real-world" use, Applicant contends that the skilled artisan would also find the assertion of utility to be substantial.

Applicant respectfully points out that Applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. Moreover, as stated in the M.P.E.P. § 2107.00 (III) at 2100-26, "[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides 'an immediate benefit' and thus satisfies that utility requirement." All that is required of Applicant is that there be a *reasonable* correlation between the biological activity and the asserted utility. *See Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980).

Moreover, Applicant respectfully reminds the Examiner that utility can exist for therapeutic inventions "despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition." M.P.E.P. § 2107(III) at 2100-27. "Usefulness in patent law . . . necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re* Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (Emphasis added).

In view of the above, Applicant asserts that one of ordinary skill in the art would consider Applicant's asserted utility of the invention, to be *specific, substantial, and credible* and would have no basis for considering these asserted utilities to be "false." "When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. §101 is clearly shown." *Raytheon v. Roper*, 724 F.2d 951, 958 (Fed. Cir. 1983). Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 25-36 under 35 U.S.C. § 101 for alleged lack of utility.

b. The Examiner has also rejected claims 25-36, under 35 U.S.C. § 112, first paragraph, for lack of enablement (*See,* page 7, second paragraph). More particularly, the Examiner states that since the claimed invention is allegedly not supported by either a specific or substantial or well-established utility, one skilled in the art would not know how to use the claimed invention.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a credible, specific, and substantial utility. The Examiner "should not impose a 35 U.S.C. § 112 , first paragraph, rejection grounded on 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. § 2107(IV) at 2100-28 (Rev. 1, Feb. 2000). Since the claimed invention complies with the utility requirement of 35 U.S.C. § 101, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims 25-36 under 35 U.S.C. § 112, first paragraph, based on alleged lack of utility of the claimed invention.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicant believes that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by the Applicant would expedite the allowance of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

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Respectfully submitted,

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